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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/087,929	03/01/2002	Clarence N. Ahlem	202.8	7989	
26551 75	90 10/06/2004		EXAMINER		
HOLLIS-EDEN PHARMACEUTICALS, INC. 4435 EASTGATE MALL			SPEAR, J	SPEAR, JAMES M	
SUITE 400	TE WILLE		ART UNIT	PAPER NUMBER	
SAN DIEGO,	CA 92121		\ 1615		

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/087,929					
Office Action Summary	Examiner	AHLEM ET AL. Art Unit				
•						
The MAILING DATE of this communication app	James M Spear Dears on the cover sheet with the	1615 correspondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be y within the statutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS fro, cause the application to become ABANDON	timely filed ays will be considered timely. m the mailing date of this communication. NED (35 U.S.C. § 133)				
Status						
1) Responsive to communication(s) filed on 25 Ju	<u>ıne 2004</u> .					
2a) This action is FINAL . 2b) ⊠ This	action is non-final.					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-14 and 46-57</u> is/are pending in the application.						
· -	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-14 and 46-57</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correcti						
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Offic	e Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents						
3. Copies of the certified copies of the prior		ved in this National Stage				
application from the International Bureau * See the attached detailed Office action for a list of	. ,,	ad				
200 mo altached dotailed office delicit for a list (or the contined copies not receiv	си.				
Þ						
Attachment(s)						
) Notice of References Cited (PTO-892)	4) Interview Summar					
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail D 5) Notice of Informal 6) Other:	Date Patent Application (PTO-152)				
Patent and Trademody Office	· · · · · · · · · · · · · · · · · · ·					

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- 1. The Information Disclosure Statements submitted January 30, 2004 and February 06, 2004 have been received but have not been fully considered. The references will be considered and indication of such will be submitted with the next office action.
- The following is a quotation of the first paragraph of 35 U.S.C. 112:
 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claims 1-14 and 46-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims remain rejected for the reasons set forth in the Office Action mailed 23 March 2004. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include, but are not limited to:
- 4. 1. The breadth of the claims; 2. The nature of the invention; 3. The state of the prior art; 4. The level of one of ordinary skill; 5. The level of predictability in the art; 6. The amount of direction provided by the inventor; 7. The existence of working examples and 8. The quantity of experimentation needed to make or use the invention based on the content of the disclosure. When the above factors are weighed, it is the examiner's position that the disclosure fails to meet the enablement requirement for the following

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reasons: Claims that recite an optionally substituted alkyl group or alkenyl group or alkynyl or aryl moiety for example without describing the substituent are considered very broad. There are numerous possible substituents. While a species has been elected, the claims are not so limited. A method to treat a blood cell deficiency encompasses a wide variety of pathological conditions. There is no evidence as to whether a single compound could treat any blood cell deficiency or whether any of a number of compounds of the general formula 1 could treat all such deficiencies. The prior art shows methods for such treatments, however the nature of the prior art is such that it would be unreasonable to have a group of related compounds capable of treating all blood cell deficiencies. It appears that one of ordinary skill in the art would first determine the blood cell deficiency and then determine the compounds having some degree of effect on said deficiency. One may predict how a related group of compounds act on a disorder however it seems the level of predictability for numerous different disorders would be low or rather difficult. The specification and examples shows different compounds matched with particular disorders however there is no evidence of a single compound having an effect on any blood cell disorder. It is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

- 5. Claims 1-14 and 46-57 are rejected.
- 6. Claims 15-45 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272

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0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic James M. Spear

Business Center (EBC) at 866-217-9197 (toll-free).

James M Spear **Primary Examiner** Art Unit 1615

October 4, 2004